

# Falsified Medicines Costing the Earth



ASOP EU strategic review of costs to the public purse due to the production and sale of falsified medicines



ASOP EU

Alliance for Safe Online Pharmacy

# Contents

<b>Forewords</b>	<b>4</b>
<b>Jim Thomson</b> Chair, European Alliance for Access to Safe Medicines	
<b>Domenico Di Giorgio, Ph. D.</b> Director of Counterfeit Prevention Unit AIFA - Italian Medicines Agency	
<b>Executive Summary</b>	<b>6</b>
<b>Scope</b>	<b>9</b>
<b>Understanding the prevalence of criminal counterfeiting activity</b>	<b>10</b>
<b>Quantifying the prevalence in the supply chain and hence the cost</b>	<b>16</b>
<b>The potential impact on Public Health</b>	<b>23</b>
<b>Conclusion</b>	<b>25</b>
<b>Recommendations</b>	<b>27</b>
<b>Annex &amp; References</b>	<b>28</b>

*“We are seeing a significant increase in the manufacture, trade and distribution of counterfeit, diverted, stolen and illicit medicines and medical devices. It is impossible to quantify the extent of the problem, but in some areas of Asia, Africa and Latin America, counterfeit medical products can form around one-third of the market.”*

**Interpol fact sheet COM/FS/2012-01/DCO-04**

*“When someone is sick, can’t afford to purchase expensive medicine or is just trying to save money, they are more likely to take a chance and buy medicines online, making themselves vulnerable to purchasing fake, illicit or spurious medical products and thus harming themselves...”*

*“Organised, sophisticated criminals and rogue pharmacies are unfortunately using the internet to defraud innocent consumers, to place them in harm’s way, to steal their identities and to engage in credit card fraud.”*

**Interpol 2012 Secretary General Ronald K. Noble**

*“As the Internet becomes increasingly accessible around the world, so the number of potential victims increases, which is why international multi-sector actions such as Operation Pangea are vital”*

**Aline Plançon 2012 Head of INTERPOL’s Medical Products Counterfeiting and Pharmaceutical Crime unit**

All available at <http://www.interpol.int/News-and-media/News-media-releases/2012/PR077>



# Foreword

The global criminal enterprise of falsified medicines has never had a higher profile. In Europe, the Falsified Medicines Directive will soon make sure that the legitimate supply chain is protected as never before. Successive covert operations coordinated by law enforcement agencies intercept shipments with increasing regularity. Yet, still, organised criminal gangs peddle their wares to an unsuspecting Public. That shows one thing beyond doubt - there is money to be made, and a lot of it.

In 2005, the Center for Medicines in the Public Interest suggested that, by 2010, the global trade in falsified medicines could be worth \$75bn (€58bn). The weight of opinion suggested that this was overestimating the scale of the market. In reality, it now looks to be an underestimate.

Of course, the view of those of us concerned with patient safety, remains that a single person harmed by a fake medicine, is one too many. However, it is not just patients who are harmed by this crime. Whole healthcare systems, manufacturers and distributors of medicines, financial institutions, insurance providers and a myriad of internet intermediaries, all suffer directly and/or indirectly as a result of falsified medicines.

The purpose of this publication is to collect - for the first time in one place - the various estimates of just how costly this crime is. It is not an exact science and, by definition, it is tremendously difficult to say accurately what the impact is of an unseen criminal activity. That said, in researching this area, ASOP EU has done a great service to all those concerned not just with patient safety, but with the good of Society as a whole. What is very interesting to note about this latest analysis is that, despite calculating costs from three different standpoints, the numbers seem to point quite robustly to an impact on the European Community of €1bn and €3bn. All three standpoint conclusions were based on conservative estimates indicating that this may be the tip of the iceberg.

Healthcare is one of the most expensive provisions of any country. It is hard enough for policy-makers to balance national needs, without significant sums of money haemorrhaging from the system. With this report, ASOP EU takes on a formidable task. It attempts to quantify the cost of a largely unseen crime, based on the best available reference material. If it has succeeded, if indeed the proceeds of the crime are remotely close to the figures proposed in this report, then perhaps the most apposite question is “How much more healthy would Society be, if it was able to rid itself of those who prey on its people?”

**Jim Thomson**

Chair, European Alliance for Access to Safe Medicines  
Member, Institute for Health Law Studies  
California Western School of Law

# Foreword

As regulators, we are primarily concerned with the safety of our citizens. Our duty is to ensure that the regulatory framework properly serves its purpose. The phenomenon of falsified medicines forces us to step outside of our comfort zone and confront what happens when serious, organised and global criminal networks target what patients have every reason to expect to be sacrosanct - healthcare.

ASOP EU has taken the step of turning over this stone to try to see what is underneath. In doing so, it has accepted an unenviable task but it has done so with determination to show - as closely as is possible with so covert a crime - the real cost to Society of falsified medicines.

All of us involved in anti-counterfeiting on a daily basis are already aware that this is an extremely lucrative criminal enterprise, even if it is not easy to calculate the damage caused to healthcare systems.

While it is valid to try to quantify the damage these criminals are doing to our finances, of course counterfeiting is not a matter for figures. It is a crime against the individual. If an unsuspecting patient unwittingly takes a falsified medicine, it is entirely possible that there will be no direct ill effects. However, it is also possible that there will be. A patient may suffer directly, and that suffering could range from a lack of the predicted treatment outcome - the condition not improving - to adverse effects caused by the ingredients used in manufacturing the “medicine” or indeed the conditions under which it was manufactured. It could result and indeed has resulted in death

Those who engage in making and selling falsified medicines have no interest whatsoever in healthcare or patient safety. They do not care about patients at all. Their only concern is how much money they can make from their crime. Until now, we have not had a clear idea of how profitable the crime is but, with this report, ASOP EU tries to put a number to it.

In spite of the difficulties, this is a valuable exercise and, of course, it should be taken seriously by policy-makers. However, it tells only a part of the story. It does not address the dilemma faced daily by all regulators. It does not tell me what I should say to a patient who has taken a medicine, in good faith, which is then found to be a fake. That breach of trust is the true cost of this crime and it is a truth that we are determined to make the criminals face up to.

**Domenico di Giorgio Ph.D**

Director of Anti-Counterfeiting Group  
AIFA - Italian Medicines Agency



## Quantifying Cost

Domenico Di Giorgio, Ph. D., Director of Counterfeit Prevention Unit AIFA - Italian Medicines Agency, is highly active and influential in the fight against the counterfeiters, as well as his agency being one of the most proactive in disseminating best practice and educating the public about the dangers of falsified medicines<sup>1</sup>. It comes as no surprise, that he quite rightly points out that counterfeiting is “not a matter for figures”.

This is based on the premise, that so far there has not been a definitive piece of research, to quantify this rising criminal phenomena.

But even more important is that this activity kills and debilitates people, young and old. Neither does it respect race, gender or social status. In this sense a single person harmed or killed, is one too many and so, actually quantifying the cost, could be argued to be an academic exercise, as it is impossible to put a price on a life.

However, the crime only exists because there are profits to be made and it is justifiable that, as we live in a rapidly evolving world and, particularly, in the online space, that we attempt to quantify this activity. We hope that this report will at the very least serve to raise the issue amongst all interested and influential parties who, in turn, can be proactive in bringing about measures to combat this crime and also raise public awareness of the dangers of falsified medicines.

Falsified medicines are found everywhere in the world and are a very lucrative criminal business. The variation in quality and type is large, ranging from medicines containing toxic substances to those containing inactive ingredients (therefore ineffective when taken). There are also marked differences in appearance, from those that clearly look sub-standard in every way to, those that even professionals find hard to distinguish from the genuine article. Often the only way to truly authenticate (or confirm the medicine as falsified) is to have the originator run complex analytical tests.

Quantifying the financial impact of falsified medicines is, by definition, a very difficult task. The organised production and sale of falsified medicines is a global criminal enterprise and the criminals engaged in it do not publish their accounts. So, in order to attempt to quantify costs, we must look to available data, combine these data and extrapolate from them. In the European context there is a body of data available to facilitate this.



## The Falsified Medicines Directive

The implementation of the Falsified Medicines Directive (FMD)<sup>2</sup> in Europe will further enhance the robustness of the legitimate supply chain. This supply chain can be characterised by licensed actors from inspected pre-wholesalers, to wholesalers or distributors, to the place of dispensing – the pharmacy - under the supervision of a qualified pharmacist. However this route to market is made more complex by the legally permitted free movement of medicines across European borders. This can mean the medicine having significant additional routes to its final destination – the patient. The FMD places additional requirements on those engaged in this activity (parallel trade) and it is encouraging that the representative body of the parallel traders (EAEPC) has played a major role in joining with other supply chain actors to ensure that the FMD is workable.

The FMD mandates that every pack of prescription (and some OTC) medicines will be uniquely identifiable and will have the additional security of a tamper evident seal. The source of active pharmaceutical ingredient (API) will also be more highly regulated, as will all actors in the supply chain.

## The Online Environment

Whilst legitimate supply will become even more secure, the opportunities for increased access to market via the internet cannot be underestimated. As more legitimate websites enter the market, it is certain that, unchecked, criminals will also migrate to this less easily policed environment. An EAASM report (The Counterfeiting Superhighway, 2008)<sup>3</sup> conclusively found that a patient buying medicines over the internet can expect a 63% chance of receiving a falsified medicine.

As more consumers buy their medicines online, it follows that distributors and retailers will develop systems to accommodate this, in turn attracting more customers. The FMD mandates awareness-raising to inform this new audience. Heightened awareness can also divert the flow to safe online pharmacies, as demonstrated by the EAASM project (Counterfeiting the Counterfeiter, 2011/12)<sup>4</sup> which helped over 12000 customers to find approved pharmacies in Germany alone, in a nine week period.

To highlight the current dire state of affairs an arbitrary web search, using the brand name of a well known erectile dysfunction prescription-only medicine (POM) revealed no less than 147 million results in 0.38 seconds. The overwhelming majority of these websites will not be registered pharmacies. Any patient unwittingly accessing such websites could be placing at risk not just their health, but also their identity. Contrary to common perception the problem is not limited to this disease category as there is clear evidence that other medicines for serious conditions are also widely advertised online by illegitimate drug-sellers.

### Fighting the Threat Together

The formation of the Alliance for Safe Online Pharmacy EU (ASOP EU)<sup>5</sup>, mirroring its US sister organisation, is an important new initiative in combating this danger. It aims to fight against those criminals who see the making and peddling of false medicines an easy way to make profits, regardless of the detrimental effect on the public health. The approach of ASOP EU is to achieve practical improvements in patient safety online through collaborative voluntary efforts by all the actors in this space. These will include action by the internet intermediaries, with agreed standards based on model voluntary protocols, combined with common standards for licensing online pharmacies in Member States where it is legal for them to exist. The Alliance and its partners will seek to take direct action to prevent illegal websites appearing and a common and accepted way – without recourse to law enforcement agencies – to remove illegal online pharmacies. The development of campaigns to raise public awareness will also be vitally important.

### The Cost to Europe of Falsified Medicines – Offline and Online

Total costs include falsified medicines bought via the traditional supply chain (offline) i.e. not via the internet, plus those bought via the internet (online). Conservative modeling, by the EC, proposes a cost of nearly €1bn (2007). However, figures published elsewhere by the EC, suggest that this may have been underestimated by 66%. If this is the case then the true cost might well be in the region of €3bn.

Taking a more empirical view of the loss of sales and therefore costs due to counterfeiting activity, a 1% incidence based on total pharmaceutical sales in Europe would equate to €2bn (Again, the 1% is not supported by robust research but one could strongly argue this is not unrealistic and it is the figure that has been suggested by the WHO)<sup>6</sup>.

To quantify the opportunities to make money via a spurious website, set up at very little cost, the EAASM project, Counterfeiting the Counterfeiter, involved the planning and promotion of a ground-breaking fake pharmacy website. This attracted patients buying online and “dispensed” patient safety information and access to the regulatory body’s list of authorised pharmacies.

Using a conservative estimate, had it been selling falsified medicines, then this single website would have netted sales of up to €35m in one year. Although online trading in prescription medicines is only legal in 4 Member States the EAASM project in Germany attracted visitors from 112 countries. Therefore it is clear that any other Member State’s policy of not offering online access to prescription medicines is no barrier to patients accessing medicines online. Extrapolating this website’s

performance to a pan-European scenario, the cost in terms of lost legitimate sales of medicines would equate to €1.4bn.

Recently LegitScript, a US based company set up to combat online pharmacy crime, demonstrated to ASOP EU that at any given time, up to 400 fake pharmacy websites can be located, carrying a .eu domain name, offering product to the European market. Multiplying 400 by €35m rounds to €1.4bn suggesting that the costs calculated from the EC data and from the EAASM project, may be reasonably accurate. Worryingly, removing the .eu suffix and replacing it with .com, yields tens of thousands of fake pharmacy websites<sup>7</sup>.

## Scope

This paper sets out to review key data relating to the criminal counterfeiting of medicines and attempts to quantify the cost to the various actors in the supply chain as well as the Public. Whilst every attempt has been made to gather the key milestone information points, It may be that some evidence of a significant nature has been omitted. If this is the case, then the calculations of the cost to Society (both public and private) of the production and sale of falsified medicines to the Public will, on balance, be likely to have been underestimated (it being highly unlikely that any omitted criminal activity actually saved public money).



Inspectors face a mammoth task in their attempts to stay one step ahead of the counterfeiters



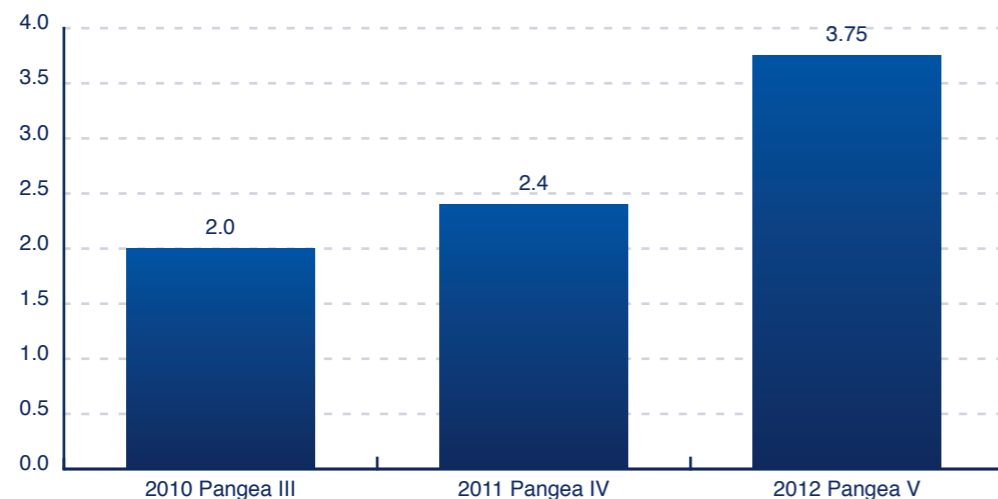
# Understanding the prevalence of criminal counterfeiting activity

## Pangea – a global initiative to protect patients from receiving falsified medicines ordered from the world wide web

- INTERPOL promotes concrete law enforcement actions in the field with the ultimate aim of protecting the public from sub-standard and dangerous goods. They are also highly active in the anti-counterfeiting of medicines
- Among the four highly effective on-the-ground operations notably Pangea, Mamba, Storm and Cobra, the Pangea operations give a good overview of the extent of criminal activity<sup>8</sup>
- The results of the last three Pangea (III to V) operations (an intensive week of anti-counterfeiting activity per year, based upon continuous planning) are summarised in the following graphs

**Graph 1** shows that the total number of pills and therefore packs seized has been increasing year on year. This does not necessarily mean that criminals are being more active as the number of countries that are becoming involved in the Pangea operations is also increasing year on year. It does tell us though that the more countries that do become involved, the more are successful authorities are in apprehending criminals.

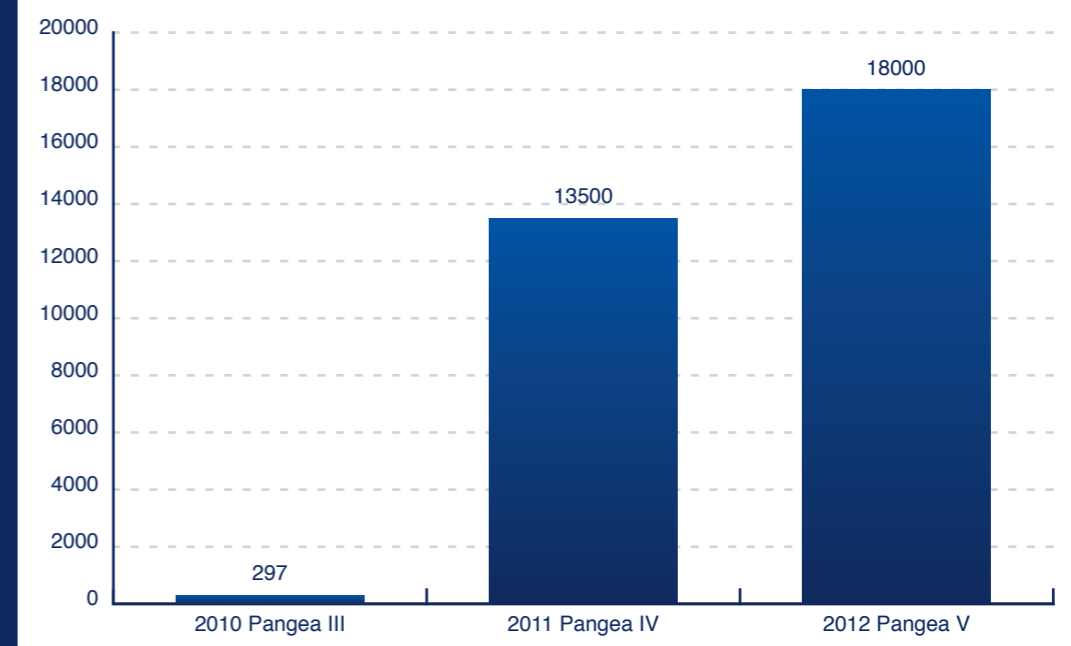
**Graph 1 - Pills of medicines seized (millions)**



# Understanding the prevalence of criminal counterfeiting activity - cont'd

**Graph 2** shows that the number of websites being taken down has greatly increased. It should be noted that there are a number of organisations now which are actively monitoring the web for fake pharmacy websites. Interpol, Europol and various national police forces have, to varying degrees, resources and expertise targeting illegal pharmacy websites. The view of LegitScript, a US based company, is pertinent in this context. It estimates that at any one time, there are over 30,000 websites marketing drugs for sale into the European Union (and many of these websites simultaneously target other regions of the world). These vary in character from brand new or rarely used Internet pharmacies with few or no sales, to websites doing a robust business<sup>7</sup>.

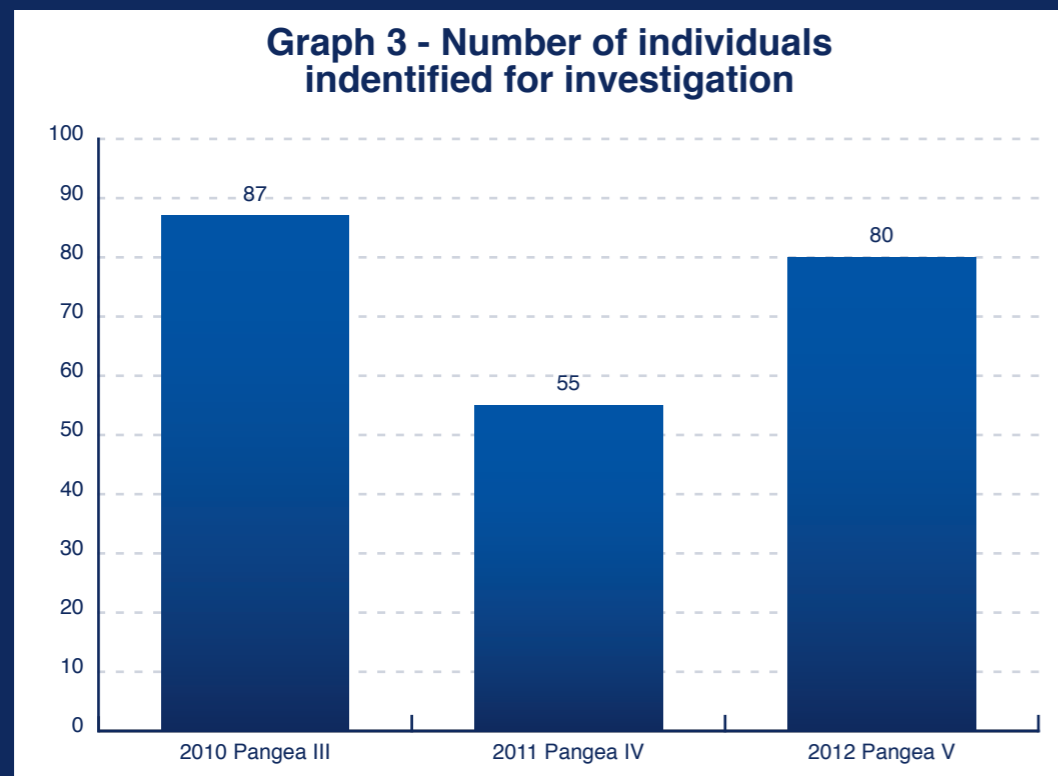
**Graph 2 - Number of websites taken down**



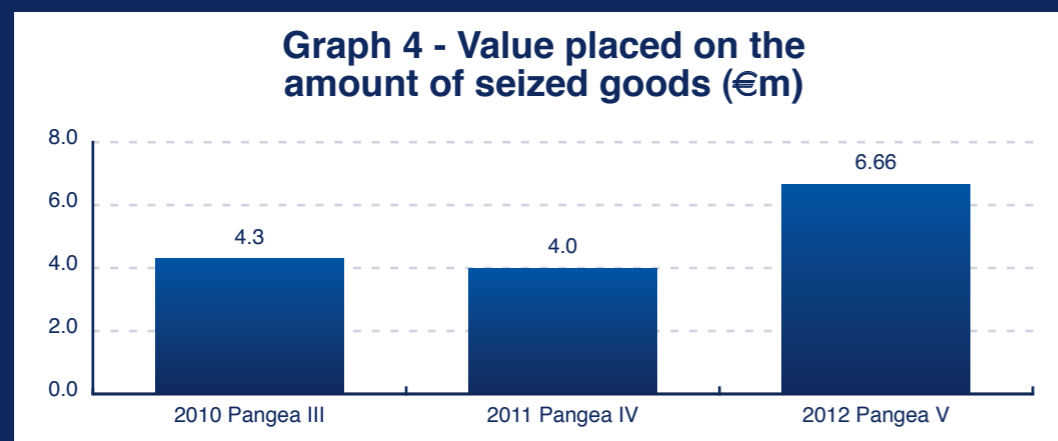
**Graph 3** looks at those individuals that have been identified for investigation. Clearly this number is difficult to interpret but it is well known that there are a small number who are involved in massive counterfeiting organisations and as such wield power and influence and have the financial means to operate highly profitably in this criminal sector.



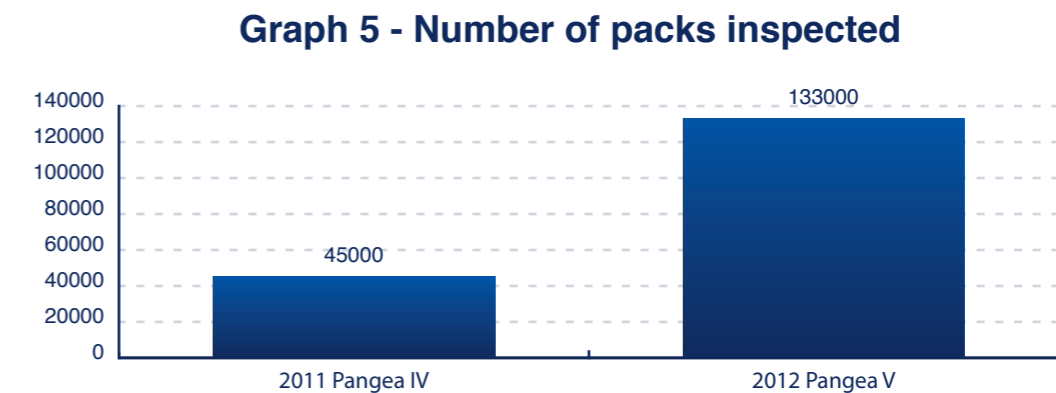
## Understanding the prevalence of criminal counterfeiting activity - cont'd



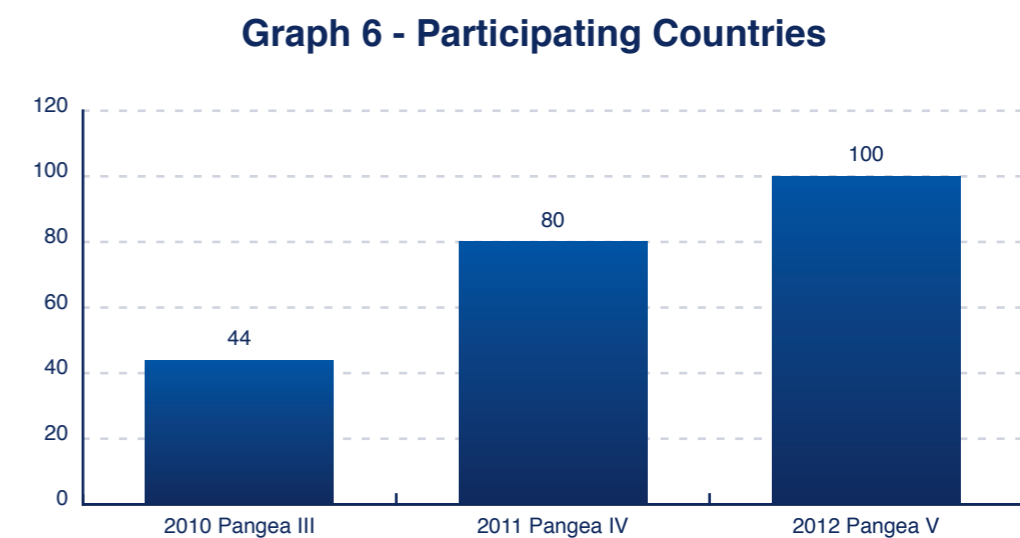
**Graph 4** is Interpol's value placed on the amount of seized goods. Clearly this is just a snapshot following an intensive period of anti-counterfeiting activity over one week per year. By projecting out to a full 52 week's activity then, the value captured could be argued to be in the region of €364m. As more consumers buy their medicines online, it follows that distributors and retailers will develop systems to accommodate this, in turn attracting more customers. The Falsified Medicines Directive mandates awareness-raising to inform this growing audience. Heightened awareness can also divert the flow to safe online pharmacies, as demonstrated by the EAASM project Counterfeiting the Counterfeiter<sup>4</sup>, which helped over 12000 customers to find approved pharmacies in Germany alone, in a nine week period.



## Understanding the prevalence of criminal counterfeiting activity - cont'd



**Graph 5** indicates the increasing number of packs that were inspected and this reflects the increased number of countries cooperating and participating in the Pangea operations.



**Graph 6** is a reflection on the growing interest amongst countries to start to tackle the rising rate of online crime. The operation has gained a lot of momentum since its inception in 2008. The first phase of the operation (Pangea I 2008) brought together 10 countries with the number rising to 100 in 2012.



## Understanding the prevalence of criminal counterfeiting activity - cont'd

### UK anti-counterfeiting activity undertaken by the Medicines and Healthcare products Regulatory Agency (MHRA)<sup>9</sup>

The MHRA is arguably Europe's most active and best-funded regulator in terms of counterfeit detection. In collaboration with the Metropolitan Police and UK Customs they have together made significant achievements, notably:

The total worth of unlicensed medicines seized by the MHRA between April 2008 and March 2009 exceeded £9 million (almost €1 million per month).

More recently and in conjunction with Metropolitan Police Central eCrime Unit and UK Border Force:

- Seizures at ports (including N Ireland) - 2.1 million doses worth £3.6 million (of which 68,000 were counterfeits)
- Websites taken down - 504 (plus 53 adverts removed on social network sites)
- Visits/inspections - 10 warrants, 2 arrests, 320,000 doses seized worth £300,000, 8 computers and correspondence seized, restraints completed or being pursued on bank accounts and 2 properties
- Total seizures in UK - 2.4 million doses valued at £3.9 million (Global total 3.75 million doses worth £6.5 million). The reality is that the high relative figure is that the MHRA is extremely effective in combating falsified medicines
- Types of medicines - very wide range of medicines seized
- SPAM Organised Crime Networks - approximately 17,000 websites taken down through meeting of experts called by MHRA targeting 7 SPAM groups in an unprecedented way



An unexpected surprise for visitors to a website taken down by operation Pangea v

## Understanding the prevalence of criminal counterfeiting activity - cont'd

### European anti-counterfeiting activity

- The European Commission, in the 2008 project "Medifake"<sup>10</sup>, targeted customs control on illegal medicines entering the EU, and recorded results of no less than approximately 1.25 million packs in a two month period
- On the basis of a risk profile disseminated by the Commission, Customs from the 27 Member States put special focus over the two month period on coordinated action to stop illegal medicines from entering the European Union
- Among the intercepted products were antibiotics, anti-cancer, anti-malaria and anti-cholesterol medicines, as well as painkillers, erectile dysfunction medicines and drug precursors
- This first EU coordinated action seized more than 34 million illegal tablets
- It also highlighted a number of ways of improving the fight against trafficking in illegal, dangerous or counterfeit goods



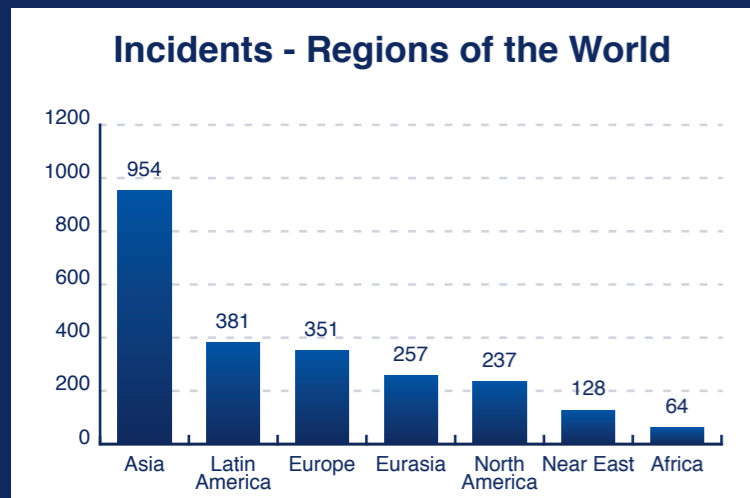
Customs Officers (and sniffer dog) inspect suspect shipments at a mail depot



# Quantifying the prevalence in the supply chain and hence the cost

It is accepted, as it is a criminal enterprise and therefore highly secretive, that estimating the total cost of counterfeiting of medicines is difficult to do. A milestone report issued in 2006 by Pitts P et al estimated that total worldwide sales of falsified medicines by the year 2010 would reach €58bn, which at the time was regarded as extreme<sup>11</sup>. However, it seems that the problem may indeed be even worse.

In 2011, the Pharmaceutical Security Institute analysed incident data in seven regions of the world. Every region did, in fact, experience a pharmaceutical crime incident. While there was a decline in incidents in Asia (which is still by far the biggest region for criminal activity), four of the seven regions recorded an increase in the total number of counterfeiting, theft and illegal diversion incidents.



The total number exceeded 1,986 incidents because a region is included if it is the “origin, point of seizure or transit, or destination” of illegal pharmaceuticals. Of these incidents the falsified medicines involved 532 different pharmaceutical products and medicines in the genito-urinary, anti-infective and cardiovascular therapeutic categories accounted for the largest number of incidents.

Therefore these were seen as having drugs which were the most frequently targeted by individuals engaged in pharmaceutical counterfeiting<sup>12</sup>.

There are tangible indicators of the growing threat to patient safety. EU customs seizures of counterfeit goods rose by 280% from 2009 to 2011, mostly due to counterfeit prescription medicines sent via mail<sup>13</sup>.

This growing threat is equally prevalent in the US. According to the January 2012 report of the U.S. Customs and Border Protection (CBP) for FY2011, seizures of counterfeit pharmaceuticals increased by 200% and those at express consignment and mail facilities have risen by 84% since 2007, due to the continued growth of websites selling counterfeit products and a marked shift towards using international mail and express courier services to transport the illegal merchandise<sup>14</sup>.

# Quantifying the prevalence in the supply chain and hence the cost - cont'd

According to the (July 2011) European Commission (EC) annual report on European Union Customs Enforcement<sup>15</sup>, the number of shipments stopped by EU Customs had doubled compared to 2010, with an 82% increase in detentions of postal traffic largely due to the increase in online purchases.

That report states that 69 percent of articles detained in postal traffic are medicines, and quotes Algirdas Šemeta, Commissioner for Taxation, Customs, Anti-Fraud and Audit as saying:



*“We have experienced a spectacular increase of detentions in the postal traffic since last year: the number of cases tripled and many of the seized goods included medicines... This upward trend reflects a growing number of online purchases”*

In a recent report by University College London, case studies offered robust qualitative evidence of the capacity of medicines falsification to harm public health across all of the WHO regions<sup>16</sup>.

## WHO, Council of Europe and EC estimations of the prevalence of falsified medicines

The WHO estimates that between 1 – 10% of medicines are spurious/falsely labelled/falsified/counterfeit (SFFC) with some areas of the world having an incidence as high as 30% or more<sup>6</sup>.

A survey carried out in 2004 by the Council of Europe revealed that 17 expert respondents, (9 EU and 8 Non EU) gave a range of between 2-20% as their in-country estimate of counterfeit medicines<sup>17</sup>.

More recently the EC Impact Assessment has estimated a much lower prevalence rate of 0.005% which equates to 1.5 million packs of counterfeit medicine in the legitimate supply chain per year<sup>18</sup>.



Sub-optimal doses in falsified medicines can encourage microbial resistance, rendering antibiotics - some of the most commonly used medicines in the world, ineffective.



## Quantifying the prevalence in the supply chain and hence the cost - cont'd

The EC based its prevalence estimate on data – where available – from national regulators. This estimate did not adequately account for the fact that, whenever there is concerted and coordinated effort on the part of enforcement authorities, unexpectedly high incidences of falsified medicines are discovered (Medifake 2008 being a prime example)<sup>10</sup>.

However this low estimated rate still equates to a very large cost to the EC as many factors need to be considered and thus the cost of falsified medicines can be broken down as follows:

- Loss of income to pharmaceutical companies (rights holders) up to 10% globally
- Indirect loss of income to rights holders, for example through reputational damage
- Loss of income to Governments (direct e.g. tax and indirect e.g. societal cost due to treating the added disease burden)
- Remedial / incidental costs (e.g. recall and disposal, restitution required to make good the supply chain)
- Cost to the overall European economy (European Commission)
- **And this does not of course take into account the human cost**

**When these criteria (based on the 0.005% penetration rate) are factored into the cost equation then, according to the European Commission, the cost to the EU is €950 million per year**

This low and optimistic rate of 0.005% was based on authorities finding only a third of the actual figure for counterfeits in the EU. So, in effect, the real cost per year could be as high as €3bn. The EC, in its Impact Assessment (looking at the legitimate supply chain), also predicted that there would be a 10% per annum increase. Taking the Pangea IV and V information it would appear that although the rate of detection of fake medicines is increasing rapidly (suggesting that the agencies may be getting more sophisticated in the way they detect this crime) there would seem to be clear grounds to indicate that the criminal activity itself is increasing exponentially.



## Quantifying the prevalence in the supply chain and hence the cost - cont'd

Even accepting the EC-proposed 10% increase per annum, the compound effect would mean that by 2020, the falsified medicines market in Europe would be worth €3.3bn. Or if the higher starting incidence figure of €3bn was taken then the cost per year by 2020 would be as high as €10.5bn.

### Potential adverse knock-on effect to the development of new medicines

Given the loss of profit within the pharmaceutical sector, it has been suggested that there could be a resultant negative effect on global health outcomes due to the reduction in innovation of new medicines. The pharmaceutical industry is at a significant crossroads. The ability to produce new innovative medicines is becoming more difficult. This can easily be measured by the reduction in new chemical entities (NCEs) over the past few years. This is despite - on average - pharmanos spending between 15 and 20% of turnover on R&D<sup>19</sup>.

The total market for medicines as measured by IMS in 2012 was €744bn<sup>16 19</sup>. Taking the higher overall WHO estimate of 10% of medicines being counterfeited or falsified then the damage to overall sales could be in the region of be €74bn. This would seem reasonable if the effect of the offset for increased costs in the developed world and that of the increased prevalence in the developing world, were to be mathematically similar.

Turning specifically to Europe then sales in 2012 were €207bn (IMS 2012) and thus the loss at the 10% incidence rate would have been €21bn. And if the more conservative figure is taken then we return to a number around €2bn which triangulates well with the EC and EAASM proposals.

The extrapolated online figure of €1.4bn (see next section) from the EAASM report is well within this range and given that it could be argued that the projections were of a conservative nature then there is an emerging pattern across estimates of a number between €1bn and €3bn.

It is important to note that sales losses go straight to the corporate bottom line causing a significant loss in profits. This may impact on strategic investment decisions for the future.

## Quantifying the prevalence in the supply chain and hence the cost - cont'd

The consequences to longer term innovation of new medicines could therefore be serious. For instance, the evolution of bacteria resistant to modern anti-biotics is a growing phenomenon. However, the anti-biotic market can be characterised in commercial terms as a market classified as aperiodic short term acute treatments. With patent lives becoming shorter and regulatory hurdles becoming more difficult, the opportunity to recoup development costs, combined with a lower overall profitability level (due to counterfeiters), may influence pharncos to focus their R&D activities on “safer” long term chronic markets.

These kinds of unquantifiable consequences due to criminal counterfeiting activity should, where possible, be factored in when calculating the cost to the Public and Private purse of the falsified medicines phenomenon.

### Calculating the cost – the illegitimate supply chain via the internet – a growing problem impacting on patient safety

In August 2011, the U.S. Department of Justice required Google to forfeit \$500 million in revenue generated by online ads for prescription drug sales by rogue online drug sellers. As CNBC and USA Today put it...

*“When \$500 million is spent by a network of independent retailers for search marketing, it is likely not a stretch to assume there is a lucrative business behind the scenes.”<sup>20</sup>*

This lucrative criminal environment was also highlighted by the European Alliance for Access to Safe Medicines (EAASM), in three separate reports into the patient safety dangers of illicit online pharmacy, further establishing the scale of the problem and the dangers of buying medicines online. The three reports deal respectively with what a patient might encounter when venturing online, the prevailing online pharmacy environment in five EU countries, and the relatively simple process a criminal might follow to create and promote an illicit online pharmacy.

## Quantifying the prevalence in the supply chain and hence the cost - cont'd



In 2008 the EAASM published the influential report “*The Counterfeiting Superhighway*”<sup>3</sup>. The project analysed purchases of prescription medicines from 100 online pharmacies and included expert and chemical analysis of over 30 packets. This research revealed that 63% of medicines were fake or substandard, 96% of pharmacies were operating illegally and 94% of websites did not have a named verifiable pharmacist. Over 90% did not require a prescription.

“*Discounted or Dangerous*”<sup>21</sup> (DOD) research by the EAASM revealed a similarly bleak picture. In the three Member States where online pharmacy is supposedly prohibited (France, Spain and Italy) 177 websites were surveyed and not one displayed a consistent URL. This is a significant risk marker. In Germany and the UK, which fared rather better, there remained alarming inadequacies. For example, in Germany, over 30% of websites surveyed did not require a prescription, whilst in the UK, 75% did not have a named pharmacist on the website (a legal requirement). This highlights the abject standards in three Member States where online pharmacy is supposedly not allowed (but seems rife) and the barely-better standards in two where the activity is legal.



The sister EAASM publication, “*Counterfeiting the Counterfeiter*”<sup>4</sup> (CTC), complements this report by demonstrating just how easy it is to attract the public to an illegitimate website, and how much money can be made by criminals preying on vulnerable patients. With the objective of raising awareness amongst the consumer/patient, the fake pharmacy website attracted no fewer than 182,602 unique visits and 12,227 visitors clicked on an icon which took them through to a list of legitimate (online and offline) pharmacies.

## Quantifying the prevalence in the supply chain and hence the cost - cont'd

The CTC report (see table below) estimated that revenues of up to €35 million could be achieved in a year from selling falsified medicines online via one website, in Germany alone. Interestingly, based on data collected by University of California San Diego (UCSD) researchers, the largest illegal online drug sellers may generate between \$1 million (€0.78m) and \$2.5 million (€1.95m) in sales every month which triangulates well with the estimate calculated from the German fake pharmacy website<sup>22</sup>.

It could be argued that this is a conservative figure, based on a maximum of 21% of customers making 1-3 purchases per annum. It is certainly true that German is not the traditional language of the global internet and that, had it been an English language resource, the website could have generated much higher projected “sales” figures. If this value represents only 25% of the online market available in Germany then extrapolating this based on the fact that Germany represents approximately 10% of the European population, then this would mean that a minimum revenue stream to the criminals who operate these websites could be in the order of...

**€1.4bn euros**  
(35 x 4 x 10 = €1.4bn)

Percentage of annual visitors making a purchase	Purchase price (€)	Revenue generated by 1 purchase (€)	Revenue generated by 3 repeat purchases (€)
7%	15	1,050,000	3,150,000
7%	50	3,500,000	10,500,000
7%	100	7,000,000	21,000,000
Total	-	11,550,000	34,650,000

Recently, LegitScript, a US-based company set up to combat online pharmacy crime, estimated that there are 400 or more websites with a .eu suffix engaged in illegal online pharmacy activity at any given time. Multiplying 400 by €35m rounds to €1.4bn which again triangulates with previous calculations.

However, this figure only includes .eu domain names and, the realistic picture is that, at any one time, there are over 30,000 websites marketing drugs for sale into the European Union (and many of these websites simultaneously target other regions of the world)<sup>7</sup>. These vary in character from brand new or rarely used Internet pharmacies with few or no sales, to websites doing a robust business. There is therefore a strong argument that illicit sales of prescription medicines will be far greater than the €1.4bn that has been extrapolated from the EAASM projected website sales which were in fact taken from conservative estimates of achieved online sales.



## The Potential impact on Public health

The most obvious cost to patients of falsified medicines is the potential harm caused by there being no, or some active ingredients, or indeed contaminated or toxic ingredients that have been added by people who have a total disregard for the health of the “consumer”. Indeed, the outward appearance of a falsified medicine - its ability to physically resemble the real thing, is actually more important to the counterfeiter than the ingredients. Hence, there are numerous examples of falsified medicines containing, inter alia, floor polish to achieve a sheen, lead-based road paint (to mimic the yellow colour of the real medicine) and other extremely harmful substances such as mercury, have killed unsuspecting buyers.

Clearly it is not in the interests of counterfeiters to harm their potential (repeat) customers. However there is an ever-growing catalogue of disasters due to counterfeiting of medicines.

In 2001, the use of diethylene glycol in paracetamol medicines resulted in no less than 200,000 deaths in China. Similarly, in the US, fake heparin entered the supply chain and it is reported that this could have been the causal factor in over 60 deaths<sup>23</sup>.

The cost in the developing world is also great.

Many patients choose to buy their anti-malarials from street corner “pharmacies”. It is a well known fact that many of these medicines contain little or no anti-malarial active ingredient. There is firm evidence that between 15 – 50% of treatments purchased in Asia or Africa for anti-malarial treatment are of a falsified nature. In 2010 malaria killed an estimated 660,000 and according to the WHO there were 219 million cases of malaria. 80% of these were in the WHO African region, and mainly claimed the lives of children under five years of age<sup>24</sup>.

The rising resistance to a standard antimalarial treatment (chloroquine) has meant that the WHO now recommends the use of a far more expensive (artesunate containing) product. However, counterfeit antimalarials have probably contributed to the emergence of resistance to artesunate, leaving many at risk of death.



## The Potential impact on Public health

Counterfeit “lifestyle” drugs and those for chronic conditions are more commonly found in richer countries, whereas falsified anti-infectives are more common in poorer, tropical countries.

Counterfeit anti-infectives containing no active ingredient ranged from common antibiotics (such as erythromycin or quinolones) to antiretrovirals, meningococcal vaccine to prevent meningitis, and antivirals such as Tamiflu. WHO expert Professor Pierre Ambrose-Thomas states

*“Counterfeiting is more than a criminal act. Manslaughter is perfectly justified to describe such an act although some prefer calling it murder.”<sup>25</sup>*

From a public health perspective, the most dangerous falsified medicines are those for tuberculosis and HIV. Here we have a continuance of the disease and thus a danger of further spreading of the life debilitating and threatening pathogens combined with the rapid emergence of drug resistance.

The rising use by the public of online pharmacies gives real cause for concern. Once a patient decides on this route he or she becomes part of a virtual network and is, in effect, “outside” of the duty of care of the legitimate health service in that country. It is inevitable that the direction of travel will be towards greater use of the internet to support all types of medical consultation, diagnosis, treatment and management.

**It therefore follows that patients should expect a commensurate quality of online vs offline standards.**

A number of initiatives are currently underway to put in place minimum standards. A good example of this is the pioneering work being done by the National Association of Boards of Pharmacies (NABP) in the US, where the use of a global top level domain name (.Pharmacy) will be used to pre-validate online pharmacies that exceed - or transcend - minimum regulatory requirements<sup>26</sup>.

*In many countries, regulatory standards in terms of online pharmacies are either invisible (that is to say that the activity is illegal) or irrelevant (that is to say that it is vibrant, flourishing, and subverts national law, as the internet acknowledges no geographical boundaries).*

## Conclusion

At the beginning of this report, we stated that identifying accurately the financial impact of falsified medicines across the EU (let alone the globe), is extremely difficult. International criminal gangs do not file their annual returns. They are not bound by law (indeed they operate outside of it). Their world is at once highly organised but simultaneously – and of necessity – chaotic.

There are projections, based on varying degrees and qualities of research, of the scale of this global criminal phenomenon. Peter Pitts (et al) of the Center for Medicines in the Public Interest, suggested as long ago as 2005, that by 2010 the global trade in falsified medicines would reach \$75bn. The suggestion was greeted with a fair amount of scepticism and, indeed, derision. It is with a measure of disappointment that we suggest that, perhaps, the ultimate irony is that Pitts et al, would seem not only to have predicted the future that came to pass, but also, if anything, to have underestimated the true cost.

Aside from the projections, there is also an amount of data, drawn from - inter alia - enforcement agencies. In its groundwork leading up to the development of the Falsified Medicines Directive, the European Commission allocated a financial value to a single instance of a patient taking a falsified medicine. Other recent publications and studies have speculated about the real cost of falsified medicines. This report has identified a certain degree of consensus.

We do not argue that the statistical analyses we have employed to arrive at the proposals herein are exact but, rather, that they are at least as reliable as the figures oft-quoted. If anything, we believe that our estimates are conservative and err on the side of caution.

**Coincidentally, in his 2005 publication, Peter Pitts said exactly the same thing.**

Using all available and reliable indicators, we believe that the falsified medicines market is costing the EU well in excess of €1bn per annum already, that this figure is set to rise, and that this marketplace will evolve. We are not just concerned about the current scale of this criminal phenomenon. We are equally concerned about its likely evolution.



## Conclusion

### **The Falsified Medicines Directive will not stop this crime.**

What it will do – through the identification of medicines at the pack level, stricter regulation and stiffer penalties – is make the traditional supply chain more secure and, therefore, less attractive to the criminal. However, it would be foolhardy to believe that the criminal will move on to another sector. He will not walk away from profits on the scale we suggest in this report.

What he most likely will do is seek new routes to market, substantially out of reach of any directive, regulation or law. As more and more healthcare information is accessed via the internet, the criminal will expand his activity in this area.

ASOP EU has been formed – at least in part – to ensure that, as this happens, he does not get a warm welcome but, rather, is greeted by stakeholders working together to prevent his access to patients. It is a fight we are ready for, and one that we must win.

Whilst researching this report, we were permitted privileged access to the resources of the pre-eminent organisation identifying rogue online drug-sellers - LegitScript. We saw live data showing that, at any given moment, over 400 criminal websites with a .eu suffix, are online, targeting and selling falsified medicines into the EU. Over 30,000 without a .eu suffix, are also online at any given time.

This is just a small part of the illegal trade that we believe is (and believe we have shown to be) costing Europe in the region of €1.4bn per annum (and probably more). It is also a market segment that, if unchecked, is certain to expand rapidly.

Finally, whilst this report attempts to collate, make sense of and, to an extent prove, the various hypotheses regarding the financial cost of falsified medicines, it is imperative that we not forget that the highest cost is the human one. People are being harmed on a daily basis by the perpetrators of a crime that remains one of the hardest to detect and least prosecuted on Earth.

We are making progress but we have a long road to travel. If the scale of financial damage proposed in these pages re-energises all of the actors that inhabit the online space, businesses small and large, patient groups, law-makers and crimefighters embarked on that journey, then we will have succeeded in our aim whilst writing them.



## Recommendations

### **Action by Internet Intermediaries**

This crime exists because criminals are able to make their falsified medicines, advertise them online, receive payment for them and have them safely delivered. Introducing legislation to disrupt this process (which mirrors exactly the legitimate supply chain) is a long term undertaking. Equally effective, would be the introduction of mutually agreed voluntary protocols for all those actors who enable these online transactions to take place, who by adopting them would effectively ostracise the criminals from the legitimate online community.

### **Specifically, we recommend:**

- **Action on the part of the internet intermediaries with (voluntarily and collaboratively) agreed standards for ensuring patient safety online**
- **A common protocol for licensing online pharmacies – in Member States where it is legal for them to exist - and the introduction of secure “White Lists” of approved online pharmacies, securely linked to a common Trust Mark. ASOP EU intends to convene an expert group to propose such a secure system**
- **Direct action, to prevent illegal websites from appearing on the internet and common methodology for removing illegal pharmacies, with effective sharing of information amongst stakeholders**
- **Rapid action to implement the internet pharmacy provisions of the EU Falsified Medicines Directive**
- **The development of campaigns of voluntary action to disrupt the activities of illegal online pharmacies, involving all supply chain actors and internet intermediaries**
- **A mechanism for patients to easily report suspicious websites to a specific body**
- **Penalties appropriate to a crime which puts public health at risk**
- **Pan-European awareness campaigns to educate patients about illegal online drug sellers**

# Annex - summary of calculations

Organisation	SCOPE	Approach to cost analysis	Cost in Euros Range
Impact on Pharmaceutical Industry Sales	Global Incidence at 10%	Global market impact - Total market for medicines €744bn (IMS 2012). Incidence at 10% (WHO) of counterfeit medicines. Damage to overall sales in the region of €74bn.	€74bn
	Global Incidence at 1%	Logic as above.	€7bn
	European Incidence at 10%	European pharmaceutical sales in 2012 were €207bn (IMS 2012) and thus the loss at the 10% incidence rate would have been €21bn.	€21bn
	European Incidence at 1%	Logic as above but at 1% incidence rate. At this more conservative figure then we return to a number around €2bn which triangulates well with the EC and EAASM estimates.	€2bn
Impact on Public Health - European Commission Estimate	European Incidence of 0.005%	<ul style="list-style-type: none"> <li>Taking the conservative incidence rate of 0.005%</li> <li>• Loss of income to pharmaceutical companies (rights holders, for example through reputational damage)</li> <li>• Loss of income to Governments (direct e.g. tax and indirect e.g. societal cost due to treating the added disease burden)                             <ul style="list-style-type: none"> <li>• Remedial / incidental costs (e.g. recall and disposal, restitution required to make good the supply chain)</li> </ul> </li> <li>• Cost to the overall European economy (European Commission)</li> </ul>	€0.95bn - €3bn
		EAASM research - Counterfeiting the Counterfeiter (CTC report) estimated that revenues of up to €35m could be achieved in a year from selling falsified medicines online via one website, in Germany alone. Extrapolations could be argued to be conservative. If this value represents only 25% of the online market available in Germany and that Germany represents approximately 10% of the European population, then this would mean that a minimum revenue stream to the criminals who operate these websites could be in the order of €1.4bn.	€1.4bn

# Annex - summary of calculations

Comments	Compounded at 10% per year up to 2020
This is potentially very damaging to the Industry and could affect long term strategic decisions in to areas such as R&D	€159bn
Impacts on profitability	€15bn
Significant impact on profitability	€45bn
Impacts on profitability	€4.3bn
This low and optimistic rate of 0.005% was based on authorities finding only a third of the actual figure for counterfeits in the EU. So one could postulate that the real cost per year could be as high as €3bn.	€3.3bn - €10.5bn
EAASM research - Discounted or Dangerous (DODs report) highlighted the poor overall standards of pharmacy websites and very little knowledge is required to create and illicit site. Recently, LegitScript (www.legitscript.com), a US-based company set up to combat online pharmacy crime and verify legitimate websites, estimated that there were currently 400 or more websites with a .eu domain name engaged in illegal online pharmacy activity. Multiplying 400 x €35m rounds to €1.4bn which again triangulates with previous calculations. However, this estimate only pertains to one top level domain. In fact, LegitScript estimates that at any one time, there are over 30,000 websites marketing drugs for sale into the European Union (and many of these websites simultaneously target other regions of the world). These vary in character from brand new or rarely used internet pharmacies with few or no sales, to websites doing robust business. There is a strong argument that illicit sales of prescription medicines will be far greater than the €1.4bn that has been extrapolated from the EAASM projected websites sales which were in fact taken from conservative estimates of achieved online sales.	€3bn

- 1) Counterfeit Medicinal products and Similar Crimes – Risk Communication ISBN 978-88-481-2662-5
- 2) Official Journal of the European Union DIRECTIVE 2011/62/EU OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL [http://ec.europa.eu/health/files/eudralex/vol-1/dir\\_2011\\_62/dir\\_2011\\_62\\_en.pdf](http://ec.europa.eu/health/files/eudralex/vol-1/dir_2011_62/dir_2011_62_en.pdf)
- 3) EAASM Report -The Counterfeiting Superhighway – the growing threat of online pharmacies (June 2008) [http://www.eaasm.eu/cache/downloads/dqqt3sge9hwssgcos440g40/455\\_EAASM\\_counterfeiting%20report\\_020608\(1\).pdf](http://www.eaasm.eu/cache/downloads/dqqt3sge9hwssgcos440g40/455_EAASM_counterfeiting%20report_020608(1).pdf)
- 4) EAASM Report 2012 Counterfeiting the Counterfeiter <http://www.eaasm.eu/counterfeiting-the-counterfeiter-report.download>
- 5) Alliance for Safe Online pharmacy EU (ASOP EU) [www.asop.eu](http://www.asop.eu) manifesto 2012 <http://asop.eu/cache/downloads/7w1zg9yy4pcs8gc8wgcg8ksgg/ASOP%20EU%20Manifesto.pdf>
- 6) WHO factsheet on counterfeit medicines <http://www.who.int/mediacentre/factsheets/fs275/en/>
- 7) LegitScript February 2013 Data on file website <http://www.legitscript.com/>
- 8) Interpol worldwide operations <http://www.interpol.int/Crime-areas/Pharmaceutical-crime/Operations/Operation-Pangea>
- 9) Press Release: MHRA plays vital role in £6.5million drugs bust and stopping spam emails <http://www.mhra.gov.uk/NewsCentre/Pressreleases/CON189211>
- 10) European commission press release - Customs: Millions of illegal medicines stopped by “MEDI-FAKE” action. IP/08/1980 [http://europa.eu/rapid/press-release\\_IP-08-1980\\_en.htm](http://europa.eu/rapid/press-release_IP-08-1980_en.htm)
- 11) Pitts P. Counterfeit drug sales to reach \$75 billion by 2010, report says. Health Care News 2005 [http://www.heartland.org/publications/health%20care/article/17948/Counterfeit\\_Drug\\_Sales\\_to\\_Reach\\_75\\_Billion\\_by\\_2010\\_Report\\_Says.html](http://www.heartland.org/publications/health%20care/article/17948/Counterfeit_Drug_Sales_to_Reach_75_Billion_by_2010_Report_Says.html)
- 12) Pharmaceutical Security Institute data <http://www.psi-inc.org/geographicDistributions.cfm>
- 13) Internet sales drive 300 per cent surge in fakes sent by post Securing Industry website <http://www.securindustry.com/pharmaceuticals/internet-sales-drive-300-surge-in-fakes-sent-by-post/s40/a1310>
- 14) U.S. Immigration and Customs Enforcement <http://www.ice.gov/doclib/iprcenter/pdf/ipr-fy-2011-seizure-report.pdf>
- 15) DG TAXUD Data [http://ec.europa.eu/taxation\\_customs/resources/documents/customs/customs\\_controls/counterfeit\\_piracy/statistics/statistics\\_2010.pdf](http://ec.europa.eu/taxation_customs/resources/documents/customs/customs_controls/counterfeit_piracy/statistics/statistics_2010.pdf)
- 16) Dr Usman Kahn and Stephan Kreutzer of Matrix Insight and Dr Jennifer Gill and Professor David Taylor of the UCL School of Pharmacy. Falsified Medicines and the Global Public’s Health UCL School of Pharmacy and Matrix Insight – Falsified medicines and the Global Public’s Health November 2012 ISBN 978-0-902936-25-6 [http://www.ifpma.org/fileadmin/content/Publication/2012/UCL-Matrix\\_Insight-Falsified\\_Medicines\\_and\\_the\\_Global\\_Publics\\_Health.pdf](http://www.ifpma.org/fileadmin/content/Publication/2012/UCL-Matrix_Insight-Falsified_Medicines_and_the_Global_Publics_Health.pdf)
- 17) Council of Europe survey Council of Europe ISBN 92-871-5863 <http://book.coe.int> [http://books.google.co.uk/books?id=cuXnTRyfGysC&printsec=frontcover&source=gbs\\_ge\\_summary\\_r&cad=0#v=onepage&q&f=false](http://books.google.co.uk/books?id=cuXnTRyfGysC&printsec=frontcover&source=gbs_ge_summary_r&cad=0#v=onepage&q&f=false)
- 18) EC Impact Assessment COM(2008) 668 and SEC9(2008) 2675 [http://ec.europa.eu/health/files/pharmacospharmack\\_12\\_2008counterfeit-ia\\_en.pdf](http://ec.europa.eu/health/files/pharmacospharmack_12_2008counterfeit-ia_en.pdf)
- 19) Pharma at the crossroads Choosing directions in a transforming healthcare [http://www.rolandberger.at/media/pdf/rb\\_press/Roland\\_Berger\\_Pharma\\_at\\_the\\_crossroads\\_20080808.pdf](http://www.rolandberger.at/media/pdf/rb_press/Roland_Berger_Pharma_at_the_crossroads_20080808.pdf)

- CFA Institute Conference Proceedings Quarterly March 2006, Vol. 23, No. 1, 7 pages <http://www.cfainstitute.org/learning/products/publications/cp/Pages/cp.v23.n1.3548.aspx> also at <http://cseweb.ucsd.edu/~savage/papers/UsenixSec12.pdf> (page 11)
- 20) The Dangerous World of Counterfeit Prescription Drugs, Toscano, P. USA Today. Web. 7 Oct. 2011. <http://www.usatoday.com/money/industries/health/drugs/story/2011-10-09/cnbc-drugs/50690880/1>
- 21) EAASM Report 2012 Discounted or Dangerous? [http://www.eaasm.eu/cache/downloads/23nvzdwsj3j4oow4ssgcw8ookwc0og8/EAASM\\_DOD\\_report\\_26.04.2012.pdf](http://www.eaasm.eu/cache/downloads/23nvzdwsj3j4oow4ssgcw8ookwc0og8/EAASM_DOD_report_26.04.2012.pdf)
- 22) University of California at San Diego <http://cseweb.ucsd.edu/~savage/papers/UsenixSec12.pdf> (page 11)
- 23) Counterfeit Medicines: Wellcome Trust, American Pharmaceutical Group. Opinion Formers’ Conference on Counterfeit Medicines: Perspectives and action. London: Wellcome Trust ISBN 978 1 84129 083 6 Further presentations on subject available at [www.apg.uk.com](http://www.apg.uk.com)
- 24) WHO World Malaria Report for 2010 [http://www.who.int/malaria/world\\_malaria\\_report\\_2011/en/index.html](http://www.who.int/malaria/world_malaria_report_2011/en/index.html)
- 25) Counterfeit Drugs: a Deadly Problem, author Dr Judy Stone - <http://blogs.scientificamerican.com/molecules-to-medicine/2012/08/20/counterfeit-drugs-a-deadly-problem/>
- 26) NABP news article .PHARMACY and NABP <http://www.nabp.net/programs/pharmacy/pharmacy-and-nabp>

## Authors’ Acknowledgements

This paper was written by Mike Isles and Jim Thomson, respectively Executive Director and Chair of the European Alliance for Access to Safe Medicines (and Secretariat to ASOP EU). We both have significant experience in this field. However, the unenviable task of trying to put a cost on a covert criminal activity would have been impossible, were it not for the work, counsel and guidance of a number of eminent experts in the various component elements of pharmacy and anti-counterfeiting.

Many people gave freely of their own time, to encourage, provide direction, review drafts and, most importantly, prevent us making elementary mathematical errors! As they often did so outside of their professional affiliations, it is not appropriate to name them individually.

You all know who you are, and we are deeply grateful for your support.





**The Alliance for Safe Online Pharmacy EU (ASOP EU) is a multi-sectoral, coalition of organisations and individuals, dedicated to making the internet a safer place for patients. To find out more about ASOP EU, please visit its website at [www.asop.eu](http://www.asop.eu)**



**The European Alliance for Access to Safe Medicines works to ensure that patients are aware of counterfeit and sub-standard medicines and unsafe medical practices and that national governments have put in place mechanisms to protect the population.**

## **Falsified Medicines Costing the Earth**

Produced in collaboration with the European Alliance for Access to Safe Medicines

**Isles M & Thomson J**

Copyright © 2013 Alliance for Safe Online Pharmacy EU

All rights reserved. No part of this publication may be translated, reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopy, recording or any information storage and retrieval system, without the written consent of the publisher.

All correspondence regarding this publication should be sent to the publisher:  
**ASOP EU c/o EAASM 1386 London Road Leigh-on-Sea Essex SS9 2UL UK**